APR 10 2014

K140648

510(k) Summary

ST AIA-PACK C-Peptide II Calibrator Set

Date: March 11, 2014

Submitter:
Tosoh Bioscience, Inc
3600 Gantz Road
Grove City, OH 43123

Contact Person:
Robert L. Wick
Regulatory Specialist
6000 Shoreline Ct., Ste. 101
South San Francisco, CA 94080
Phone: 650-636-8117
Fax: 650-636-8121
Email: Robert.Wick@Tosoh.com

Device Name: ST AIA-PACK C-Peptide II Calibrator Set

Classification:
Class II
JIT
Clinical Chemistry
21 CFR 862.1150

Predicate Device:
K951848
Tosoh Bioscience, Inc. (previously known as Tosoh Medics, Inc.)
ST AIA-PACK C-Peptide (Calibrator Set)

510(k) Summary

ST AIA-PACK C-Peptide II Calibrator Set

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Device Description:

2 x 1 mL
ST AIA-PACK C-Peptide II Calibrator (1) 0 ng/mL
Protein matrix containing no detectable concentration of C-peptide with sodium azide as a preservative (Liquid).

2 x 1 mL
ST AIA-PACK C-Peptide II Calibrator (2) 0.5 ng/mL (approx.)
ST AIA-PACK C-Peptide II Calibrator (3) 2 ng/mL (approx.)
ST AIA-PACK C-Peptide II Calibrator (4) 6 ng/mL (approx.)
ST AIA-PACK C-Peptide II Calibrator (5) 15 ng/mL (approx.)
ST AIA-PACK C-Peptide II Calibrator (6) 33 ng/mL (approx.)
Protein matrix containing the assigned concentration of C-peptide (described on each vial) (Lyophilized).

ST AIA-PACK C-Peptide II Calibrator Set P/N # 025383

The ST AIA-PACK C-Peptide II Calibrator Set is designed specifically for use on the Tosoh AIA System Analyzers which have been previously cleared as a family of instruments under K971103. Only materials obtained from Tosoh should be used. Materials obtained elsewhere should not be substituted since assay performance is characterized based strictly on Tosoh materials.

The ST AIA-PACK C-Peptide II Calibrator Set is designed for use with ST AIA-PACK C-Peptide II, ST AIA-PACK C-Peptide Sample Diluting Solution, AIA-PACK C-Peptide Control Set.

Device Intended Use:

The ST AIA-PACK C-Peptide II Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK C-Peptide II assay.

Substantial Equivalence:

Comparison between the Tosoh ST AIA-PACK C-Peptide II Calibrator Set and the Tosoh ST AIA-PACK C-Peptide Calibrator Set

Similarities

Characteristic	Tosoh AIA-PACK C-Peptide II Calibrator Set	Predicate Tosoh AIA-PACK C-Peptide Calibrator Set (K951848)
Intended Use	The ST AIA-PACK C-Peptide II Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK C-Peptide II assay.	The AIA-PACK C-Peptide Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK C-Peptide Assays.
Analyte	C-Peptide	C-Peptide
Analyzer	Tosoh AIA Systems	Tosoh AIA Systems
Levels	Six (0, 0.5, 2, 6, 15, 33 ng/mL approximately)	Six (0, 0.5, 2.0, 6.0, 15.0, 30 ng/mL approximately)
Format	Lyophilized Six bottles, one for each of the six calibrator levels	Lyophilized Six bottles, one for each of the six calibrator levels
Storage	Store upright and refrigerate at 2 to 8°C	Store upright and refrigerate at 2 to 8°C
Stability (unopened vial)	Stable until the expiration date stated on the label when stored at 2 - 8°C	Stable until the expiration date stated on the label when stored at 2 -8°C
Shelf-life	12 months when stored unopened and refrigerated at 2-8°C	12 months when stored unopened and refrigerated at 2-8°C
Calibration Stability	Stable up to 90 days	Stable up to 90 days

Differences

Characteristic	Tosoh AIA-PACK C-Peptide II Calibrator Set	Predicate Tosoh AIA-PACK C-Peptide Calibrator Set (K951848)
Base	Contains sucrose	Does not contain sucrose
Stability (opened vial)	Vial is stable at 2 - 8°C for 1 day after initial use	Vial is stable at 2 - 8°C for 7 days after initial use

Summary of Traceability

The ST AIA-PACK C-Peptide II Calibrator Set contains assigned concentrations of C-peptide. The assigned value is determined on a lot-by-lot basis and is designed to provide an assay calibration range of 0.02 to 30 ng/mL of C-peptide. The calibrators in this set have been standardized against WHO 1st IRP 84/510.

Summary of Stability Studies

Three different lots of ST AIA-PACK C-Peptide II Calibrator Set were used as samples for the shelf life stability study. Each specimen was assayed in 5 replicates and the mean and CV % were calculated. The study was initiated within one month from manufacture the evaluated reagents, then assayed at 3, 6, 9, 12 and 13 months after the day of the first assay. The criterion for recovery was within 100 +/- 10%. The criterion for reproducibility (CV %) was </= 10%. The recovery was within 100 +/- 10% and the reproducibility (CV %) was </=10% at 13 months, the shelf life of the ST AIA-PACK C-Peptide II Calibrator Set was set at 12 months at 2-8° C from the date of manufacturing.

The in use stability study for the ST AIA-PACK C-Peptide II Calibrator Set was conducted at one site using one AIA-2000 analyzer and a single lot of calibrator. Three sets of calibrator material were opened and reconstituted at day 0, day 1 and day 2 before the measurement. The reconstituted calibrator vials were sealed and refrigerated for 1 day and 2 days. Urine, serum and EDTA plasma specimens were chosen for this study. Specimen aliquots were stored at less than - 70° C. Each specimen was assayed in 5 replicates. The criterion for recovery was 100 +/- 10%. The criterion for reproducibility (% CV) was </= 10%. Since the recovery and the reproducibility meet the acceptance criteria for 2 days at refrigerator temperature, the in use stability of the ST AIA-PACK C-Peptide II Calibrator Set after reconstitution, was set as 1 day (24 hours).

When stored unopened and refrigerated at 2-8 °C, the Calibrator Set is stable until the expiration date on the label. The calibrators should be used within 1 day of opening or reconstituting, provided the vials are kept tightly sealed and refrigerated at 2-8 °C.

Summary of Value Assignment

The primary reference material was prepared by diluting the C-peptide with calibrator base and its value of C-peptide as reference material was assigned based on C-Peptide of Human Insulin, International Reference Reagent using ST AIA-PACK C-Peptide II. The value of the secondary reference material was assigned using the AIA instruments with the primary reference material as calibrator. The value was verified by comparing measured results with those obtained with the previous lot for patient samples. The values of the product calibrator were assigned using the Tosoh AIA instruments with the secondary reference material as calibrator. The values were verified by comparing measured results with those obtained with the previous lot for control materials.

Conclusion:

The Tosoh Bioscience, Inc. ST AIA-PACK C-Peptide II Calibrator Set is substantially equivalent to the Tosoh Bioscience, Inc. ST AIA-PACK C-Peptide Calibrator Set k951848 for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK C-Peptide II assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

TOSOH BIOSCIENCE, INC.
C/O ROBERT L. WICK
6000 SHORELINE COURT
SUITE 101
SOUTH SAN FRANCISCO CA 94080

Re: k140648
Trade/Device Name: ST AIA-PACK C-Peptide II Calibrator Set
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: March 11, 2014
Received: March 13, 2014

Dear Mr. Wick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k140648

Device Name
ST AIA-PACK C-Peptide II CALIBRATOR SET

Indications for Use *(Describe)*

The ST AIA-PACK C-Peptide II Calibrator Set is intended for In Vitro Diagnostic Use Only for the calibration of the ST AIA-PACK C-Peptide II assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."